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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,998	09/29/2005	Yasuhiko Tabata	3691-0119PUS1	8785
2292 7590 02/28/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER SAOUD, CHRISTINE J				
ART UNIT 1647		PAPER NUMBER		
NOTIFICATION DATE 02/28/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/528,998

Applicant(s)

TABATA ET AL.

Examiner

Christine J. Saoud

Art Unit

1647

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 1-2 and 3-4 (in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-4 (in part) is/are rejected.
- 7) ☒ Claim(s) 3-4 (in part) is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claims 1-4 are pending. Claim 3 has been amended as requested in the amendment filed 27 November 2007. Claims 1-2 and claims 3-4, in part, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07 June 2007.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 27 November 2007 have been fully considered but they are not deemed to be persuasive.

Claim Objections

Claims 3 and 4 are objected to because of the following informalities: they include non-elected subject matter. Appropriate correction is required.

Applicant did not respond to this objection. If corrective action is not taken in the next response, it may be held as non-responsive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,732,738 (Komeda et al.).

Komeda et al. teach the treatment of patients with coronary artery disease by the administration of bFGF in a gelatin hydrogel (see column 1-2). Therefore, the claims are anticipated by the prior art of record.

Applicant argues that Komeda et al. only mentions in the Background section that bFGF has the benefit of enhancing sternal healing via angiogenic effects and therefore, Komeda et al. does not expressly or inherently disclose methods of treatment as currently claimed.

Applicant's argument has been fully considered, but is not persuasive. The patient population of Komeda et al. is one with coronary artery disease and they are being treated with bFGF in a gelatin hydrogel (which is crosslinked prior to addition of bFGF - see column 5, lines 39-49 and at column 7, lines 20-36). While Komeda et al. do not specifically state "coronary artery narrowing or blockage", this would be inherent to the patient population which is being treated by Komeda et al., therefore, the claims are anticipated by this reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/13710 (Jennings et al.) in view of Ikada et al. (U.S. Pat. No. 6,831,058).

The disclosure of Jennings et al. is as provided above. Jennings et al. does not specifically recite the hydrogel as being gelatin.

Ikada et al. teach hydrogels of gelatin containing bFGF. The bFGF hydrogel is useful for treating a number of conditions, including promotion of vascularization. Because Jennings et al. teach that bFGF containing hydrogels would be useful for the treatment of coronary artery disease, it would have been prima facie obvious to use hydrogels of gelatin containing bFGF, as taught by Ikada et al., in the method of Jennings et al. for the treatment of coronary artery disease because Ikada et al. teach that their hydrogels are useful for promotion of vascularization. One would be motivated to use the hydrogels of Ikada et al. because Ikada et al. teach the benefits of the gelatin-bFGF hydrogels. One would have a reasonable expectation of success in using the hydrogels of Ikada et al. in the method of Jennings et al. because the compositions appear to be very similar and have similar biological properties. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant argues at page 5 of the response that Jennings '710 does not teach a hydrogel which is crosslinked. Applicant's argument has been fully considered, but is not persuasive. Jennings et al. was cited for the teaching of treatment of coronary artery disease by administration of bFGF in a hydrogel. Ikada et al. was cited for the teaching of bFGF in a crosslinked gelatin hydrogel.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues at pages 5-6 that Ikada mentions that bFGF may be slow released for inducing angiogenesis, but does not disclose or suggest all of the elements of claim 3. Applicant's arguments have been fully considered, but are not persuasive. If Ikada et al. had taught each and every element of claim 3, a rejection of anticipation would have been made over the Ikada et al. reference.

Applicant asserts that the claimed invention is the first demonstration that crosslinked gelatin hydrogel containing bFGF can be retained in an actively moving organ such as the heart and that this demonstrates a remarkable and unexpected therapeutic effect for the claimed methods. Applicant's assertion is noted, but Applicant is arguing limitations which are not present in the claim - namely that the gelatin hydrogel is implanted into a particular area such as the heart. The current claims only state that the preparation is administered to a patient and fails to delineate any particular location for the hydrogel.

Conclusion

No claim is allowed.

This application contains claims 1-2 and 3-4 (in part) are drawn to an invention nonelected with traverse in the reply filed on 07 June 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/

Primary Examiner, Art Unit 1647